



**Administrative Closure
Alleged Delayed Diagnosis and Treatment,
Poor Communication, and Staff Insensitivity
VA Palo Alto Health Care System (640/00)
Palo Alto, CA
MCI# 2013-03176-HI-0453**

On May 31, 2013, the VA Office of Inspector General's Hotline Division received allegations from a complainant (b)(3);5 U.S.C. App 3 (IG Act); (b)(6) alleging that a lost biopsy specimen resulted in (b)(6) delayed diagnosis and treatment and that staff failed to notify (b)(6) of the lost specimen in a timely manner. The complainant also reported having overheard employees make insensitive remarks about veterans during a visit to the facility to obtain medications.

Background

The facility is a tertiary medical center. It provides primary and secondary medical, surgical, neurological, psychiatric, spinal cord injury, long term, and rehabilitative care. The facility has 438 hospital beds and 360 CLC beds. It is part of Veterans Integrated System Network (VISN) 21.

The patient is a man (b)(6) with a long history of elevated liver function (LF) tests and iron studies who had been essentially asymptomatic. In 2009, he had an ultrasound that revealed fatty liver disease. From 2010 through 2012, the patient was regularly seen in clinic, and clinicians monitored LF and iron studies results. Additional testing was performed to determine the cause of the elevated LF tests and iron studies. In early January 2013, a genetic testing for hereditary hemochromatosis (HHC)¹ showed the patient to be a compound heterozygote carrier for mutations C282Y and H63D, which identified him as either affected or at risk for HHC.

At the end of January 2013, the patient underwent a liver biopsy to help determine if he had fatty liver and/or HHC. The facility laboratory reported that the biopsy showed Stage 1 fibrosis and a moderate to severe increase in iron. The biopsy results did not definitively diagnose HHC. The patient's provider requested that the liver biopsy specimen be sent to an outside laboratory for an iron index study to better determine the degree of iron overload. The test was not done because the facility laboratory lost the liver biopsy specimen. The facility notified the patient in May of the lost specimen.

Despite not having a definitive diagnosis of HHC, the provider continued to monitor the patient's stored iron by measuring ferritin levels.² The ferritin level rose and exceeded

¹ Hemochromatosis is a disorder that occurs when an excessive amount of iron is stored in the body.

² Ferritin is a protein that binds to iron; it is found in the liver, spleen, skeletal muscles, and bone marrow. The amount of ferritin in the blood reflects how much iron is stored in the body; normal level is 22–350 ng/ml.

1,000 ng/ml. Due to the elevated ferritin levels, therapeutic phlebotomy³ treatment was initiated in early July and performed weekly thereafter with the goal of maintaining hemoglobin (Hgb) less than 12.5 or ferritin less than 20 mg/ml. In July 2013, a hematology physician documented that “the patient understands that his genotype does not necessarily mean that he has HHC. However, given these mutations he may be predisposed to iron overload, which his ferritin and liver biopsy confirm.”

Since the initiation of the weekly therapeutic phlebotomies, the patient’s ferritin and Hgb levels have normalized.

Date	6/27/13	7/22/13	7/30/13	8/20/13	9/3/13	10/1/13	10/15/13	11/4/13	1/19/13	12/3/13	1/21/14
Ferritin Level (ng/ml)	1045	519	351	231	99	32	12	11	10	14	19
HGB g/dL	16.3	14.7	14.4	13.8	13.1	13.4	12.0	12.9	13.3	13.8	15.4

Table: June 2013 to January 2014 Ferritin and Hgb Levels

Source: OIG

Findings

We substantiated the allegation that the facility lost the liver biopsy specimen; however, the loss of the biopsy did not significantly impact the patient’s long-term health. The patient received appropriate treatment despite not having a definitive diagnosis. Phlebotomy was initiated, which is the treatment of choice for iron overload disorder and/or HHC. Clinicians reviewed the patient’s case in the context of the lost biopsy specimen and determined that a repeat biopsy was not warranted at this time.

We substantiated lapses in communication between the lab and provider, as well as the patient, in relation to the lost specimen. The patient reported that he was told only that the results were not yet available when he called for the test results. The provider reported that he was told the same on each of his several contacts with the laboratory inquiring about the results of the iron index study.

We determined that the laboratory could not locate the specimen as early as February 7, which was the date of the request for the iron index study. The laboratory confirmed that the specimen was probably misfiled and that they had conducted two extensive searches without success. The pathologist told us that he notified the provider of the missing specimen but did not document this notification. As a result of this incident, laboratory procedures have been modified and lost pathology specimens are now tracked and reported.

³ Phlebotomy is a procedure to remove blood from the body. The usual course of treatment involves the removal of one unit of whole blood once or twice weekly. Phlebotomy continues until all excess iron is removed.

At the end of April, the pathologist informed the provider that the specimen had been misplaced and was not available to be sent out for testing. The provider requested that the laboratory make another attempt to locate the missing specimen. In May—when all efforts to locate the missing specimen failed—the patient was notified that his biopsy specimen had not been sent out as ordered because the laboratory had lost the specimen.

We did not substantiate that staff made insensitive remarks about veterans. We reviewed patient advocate records and found no evidence to support the allegation. The patient requested that staff undergo sensitivity training, which we confirmed is offered through Ethics training. As of August 2013, facility managers reported that approximately 95 percent of the staff has attended Ethics training.

Conclusions


We substantiated that the facility lost the patient's liver biopsy specimen. However, we did not substantiate that this resulted in a delay in management of the patient's iron overload condition. Despite not having a definitive diagnosis of HHC, we concluded that the patient received appropriate treatment for his iron overload condition.

We substantiated that laboratory staff delayed notifying the provider and patient of the lost specimen. Laboratory staff should have notified the provider the moment it was determined that the specimen was missing and could not be located.

Although we did not substantiate the allegation that staff made insensitive remarks about veterans, the facility provided evidence that most facility staff had completed Ethics training.

We concluded that the facility had already taken measures to address issues related to pathology specimens, timely provider and patient notification, and documentation of contacts in the medical record.

We have no recommendations; therefore, I am administratively closing this case.


JOHN D. DAIGH, JR., M.D. 4/1/14
Assistant Inspector General for
Healthcare Inspections